



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2002

Mr. David Buddingh
Vice President
Otres, LLC
4225 Naperville Road
Lisle, Illinois 60542

Re: K003517

Trade/Device Name: Otres toothbrush Sanitizer
Regulation Number: 872.6855
Regulation Name: Ultra Violet Sanitation/Sterilization (for toothbrushes) Unit
Regulatory Class: I
Product Code: MCF
Dated: March 4, 2001
Received: March 13, 2001

Dear Mr. Buddingh:

This letter corrects our substantially equivalent letter of June 6, 2001, regarding the classification of the Otres Toothbrush Sanitizer. The corrected regulatory class is I.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

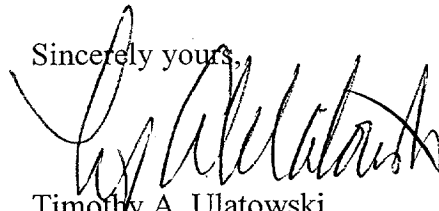
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Section D – Statement of Indications for Use

Ver/ 3 - 4/24/96

Applicant: OTRES LLC

510(k) Number: K003517

Device Name: OTRES Toothbrush Sanitizer

Indications For Use:

The OTRES Toothbrush Sanitizer is designed to sanitize up to four manual toothbrushes between uses.

The Sanitizer is intended for home use and will be available "over the counter".

The device complies with 21 CFR 801.415 "maximum acceptable levels of ozone".

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003517